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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/991,001	11/14/2001	Michael L. Bell	1840-045	4728
47626	7590	12/27/2007		
BECKMAN COULTER INC. C/O SHELDON MAK ROSE & ANDERSON 100 East Corson Street Third Floor PASADENA, CA 91103-3842			EXAMINER HAQ, SHAFIQUL	
			ART UNIT 1641	PAPER NUMBER
			MAIL DATE 12/27/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/991,001	BELL ET AL.	
	Examiner	Art Unit	
	Shafiqul Haq	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-11 and 22-44 is/are pending in the application.
- 4a) Of the above claim(s) 2-6, 8-11 and 22-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7 and 29-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Claims

1. Claims 2-11 and 22-44 are pending. Claims 2-6, 8-11 and 22-28 are withdrawn from further consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.
2. Claim 7, 29-36 and new claims 37-44 are examined on merits.

Specification

3. The disclosure is objected to because of the following informalities: Blanks or missing text: filing date and serial number is missing in line 22 of page 12 of the specification.

Appropriate correction is required.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 7 and 29-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over McDevitt et al (US 6,680,206 B1) in view of Engh et al (US 5,747,349) and further in view of Bell (US 6,165,796).

McDevitt et al. disclose plurality of sensitive particles (sensor particles) for identification of multiple analytes in a sample (see title and abstract and column 4,

lines 35-49 and claims 2-3). The particles may include various receptor molecules such as DNA (nucleic acid sensor), enzymes (enzyme sensors), antigens and antibodies (antigen-antibody sensor) to bind analyte of interest (column 5, lines 35-49; column 15, lines 63-67 and column 16, lines 1-12; column 20, lines 31-35, 54-57 and claims 20, 27-33) and to create a modulated signals (e.g. fluorescence) (column 15, lines column 18, lines 22-24, 66-67; column 19, lines 1-31 and claims 25, 26 and 36). The reagent also comprises ion sensor particles (e.g. for detection of pH, alkaline earth metal ions such as Ca^{+2}) (column 17, lines 31-45; examples 1, 2 and claims 22-23) and metabolite sensor particles (e.g. for detection of saccharides) (column 6, lines 14-19 and claim 24) that interact with specific ions or metabolite to emit detected signals (e.g. fluorescence) (column 19, lines 9-31; column 24, lines 23-26, lines 56-61 and column 26, lines 17-23).

McDevitt et al. disclose plurality of sensitive particles arranged in an array format but fail to disclose different classes of sensor particles as mixture in a fluid and use of target ionophore with ion-sensor particle.

Van den Engh et al. disclose mixture of reagents in a fluid comprising different reporter beads (sensor particles: e.g. ion sensor particles, metabolite sensor particles) for assaying multiple analytes in a sample (see abstract). Van den Engh et al. disclose that ion sensor particles interact specifically with analyte selected from group consisting of alkali metal ions (column 3, line 8) and metabolite sensor particles interact specifically with analyte selected from group consisting of saccharide such as glucose (column 3, lines 10-11). The reference further disclose

antigen-antibody coated fluorescent beads (antigen-antibody sensor particles) in the background (column 1, lines 50-67) and disclose that beads tagged with different reporter molecules (sensor particles) can be mixed with one sample and plurality of analytes can be measured simultaneously (column 2, lines 40-42). Van der Engh further disclose sensor particle useful for use in a flow cytometer (see summary of invention).

Van den Engh et al. also disclose several advantages of using mixture of different reporter beads in a fluid. One advantage is that the measurement does not require incubation, washing, or filtration steps; reporter beads can be mixed with a fluid sample and the fluorescence measured without further processing. Other advantage is that beads tagged with different reporter molecules can be mixed within one sample and a plurality of analytes can be measured simultaneously.

Therefore, given the above advantage of using mixture of reporter beads in a fluid for detection of multiple analytes, it would have been obvious at the time of the invention to a person of ordinary skill in the art to use plurality of sensor particles of McDevitt et al. in a mixture format as taught by Van den Engh to detect multiple analytes in a sample efficiently with less manipulation, with a reasonable expectation of success because Van den Engh et al. teach common reaction environment for analyzing multiple analytes in a mixture.

With regard to ionophore, Bell discloses an assay for detection of target ion using ion sensor particle (optodes) associated with target ionophores and indicator ionophores wherein the target ionophore is capable of complexing with target ions in

the sample (see summary of invention in column 1). Bell discloses that the optodes, due to small size are usable as any other flowable reagent used in commercial analyzed and thus are compatible with reagent based systems used for organic compounds. Bell further discloses that optodes are inexpensive and disposable, so they need not be cleaned and reused and this greatly simplifies commercial clinical detection systems Column 2, lines 23-33). Bell further discloses that the invention can be used with chromionophores as well as with fluoroionophores (column 3, lines 43-50) and discloses various target ionophores (see table I) and indicator ionophores (see table II) can can be used with the system.

Therefore, give the above fact that optodes as described above (Bell) efficiently detects target ions in a sample and is inexpensive and greatly simplifies commercial clinical detection system, one of ordinary skill in the art at the time the invention was made, would be motivated to include/substitute the ion sensor particle of Bell in the mixture of sensor particles as described above (McDevitt et al. in view of Van den Engh).

The features of the dependent claims are either specifically described by the references or constitute obvious variations in parameters which are routinely modified in the art (e.g. buffer conditions) and which have not been described as critical to the practice of the invention. As for dependent claim 29, Bell discloses that target ions can be selected from the group consisting of sodium, potassium, calcium, ammonium and chloride. As for claims 31 and 40-44, Bell discloses that the invention can be used with chromionophores as well as with fluoroionophores

(column 3, lines 43-50) and discloses various target ionophores (see table I) and indicator ionophores (see table II). As for claims 30 and 32-33, McDevitt discloses metabolite sensor for detection of saccharides and sugar molecules (column 6, lines 15-20 and column 25, line 60 to column 26, line 23). As for claim 31, Bell discloses plurality of optodes (column 2, lines 45-56). As for claims 34-36, McDevitt et al. disclose that particle molecules may include different receptor molecules such as DNA, RNA, proteins, enzymes, oligopeptides, antigens and antibodies (column 5, lines 33-49). As for claims 37-39, Van Den Engh et al. disclose HEPES buffer (column 9, lines 35-37 and lines 55-58). However, a particular buffer system suitable for the mixture of sensor particles can be obtained by routine optimization and have not been described in the specification to be critical to the practice of this invention (as for example, different buffers can be used HEPES, TRIS) and thus can be determined by routine experimentation and therefore, would have been obvious to one of ordinary skill in the art to discover an optimum value of a result effective variable. "[W]here the general conditions of claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." Application of Aller, 220 F.2d 454, 456, 105 USPQ 223, 235-236 (C.C.P.A. 1955). "No invention is involved in discovering optimum ranges of a process by routine experimentation." In re Aller, 220 F.2d 458, 105 USPQ at 236-237. The "discovery of an optimum value of a result effective variable is a known process is ordinary within the skill of the art." Application of Boesch, 617 F.2d 272, 276, 205 USPQ 215, 218-219 (C.C.P.A. 1980).

Response to Argument

6. Applicant's arguments filed 10/1/07 have been fully considered but the arguments are rendered moot in view of the new grounds of rejections as described in this office action necessitated by Applicants' amendments.

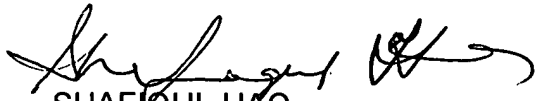
Conclusion

7. No claims are allowed.
8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shafiqul Haq whose telephone number is 571-272-6103. The examiner can normally be reached on 7:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Art Unit: 1641



SHAFIQUL HAQ
EXAMINER
ART UNIT 1641



LONG V. LE 12/21/07
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